No. 5

In the Supreme Court of the United States

OCTOBER TERM, 1943

THE UNITED STATES OF AMERICA, PETITIONER,

vs.

JOSEPH H. DOTTERWEICH, RESPONDENT

ON WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE SECOND CIRCUIT

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By informations filed in April and August, 1940, in the United States District Court for the Western District of New York, the respondent, and the Buffalo Pharmacal Company, Inc., were charged in separate counts with violations of the Act of Congress known as the Federal Food, Drug and Cosmetic Act, in that they unlawfully introduced and delivered for introduction in Interstate Commerce a consignment of a drug known as "Digitalis," which shipment consisted of one thousand pills of digitalis, which purported to represent on the label of the container thereof that the tablets were the strength or potency of one and one-half grains, when in fact the pills were not of that potency or strength.

In the second count it was claimed that the said digitalis was misbranded in that it was represented upon the label attached to the bottle containing the said digitalis a statement that it contained digitalis of the potency of one and one half grains and in fact it did not and, therefore, the branding was "false and misleading."

The third information, referred to the introduction into Interstate Commerce, pursuant to the same Act, of a drug which it is claimed was also misbranded; to wit: tablets of cascara compound (Hinkle), which was marked on the label attached to the bottle containing the article and which was "false and misleading," in that the said statement purported and represented that the said article consisted of tablets of compound cascara (Hinkle), which is a drug recognized in the National Formulary under the name "Compound Pills of Cascara (Hinkle)," whereas in truth and in fact the said article did not consist of tablets of compound cascara (Hinkle), in that the said article contained a strychnine sulphate ingredient, which is not included in the formula set forth as the standard for compound pills of cascara (Hinkle pills) in the said National Formulary.

These informations were filed by the United States District Attorney for the Western District of New York, not on his own initiative, but at the request or demand of the Department of Agriculture. We hold this fact to be important and it is not disputed by the Government.

The case came on for trial before the Hon. Harold P. Burke, Judge of the United States District Court for the Western District of New York, and a Jury, and the trial lasted about three days. The Jury's verdict, after having the case under consideration for about eight hours, was one finding the individual Joseph H. Dotterweich, the respondent here, guilty on all three counts of the Informations, and disagreed as to the corporate defendant. An

appeal was thereupon taken by the respondent here to the United States Circuit Court of Appeals for the Second Circuit and the convictions as to him were there reversed. The Government now appeals after obtaining certiorari. The jurisdiction of this Court is not questioned.

STATEMENT

Throughout the trial of this case, and now, the Government has taken the attitude, properly, that there is no question of the good faith of this respondent nor the corporation which was on trial with him in the District Court, but contends that the question of good faith and the fair dealing and the integrity of either the corporation defendant or the respondent here is not pertinent to the issue of whether or not they, or either of them, were guilty of the crime charged. Therefore, at every stage of the case, when it was sought to establish the good faith, honest dealing, integrity and fairness on the part of the defendants, upon objection of the District Attorney who tried the case, the matter was ruled out. This happened numerous times during the trial of the case. A fair illustration is found in the record—R. 291.

> "The Court: Do you want to know about the good faith of the Buffalo Pharmacal Company?
>
> Mr. Doran: I make no claim of that.
>
> Mr. Fleischmann: I started out to say that we will prove that we used the very best stuff—
>
> The Court: I see no need for this argument. It makes no difference if you have some other argument, I will be glad to listen to it. In view of the Stature, no matter what the intentions were, no matter how good their reputation was, it is immaterial. The Statute makes it so."

Arner & Company, the Government's witness, was being cross-examined:

"Q. Based on the evidence that you heard, will you tell me what you or the Buffalo Pharmacal Company, under those circumstances, could have done or not have done?

A. I know very well what I would have done. Mr. Doran I object to the question. The question of good faith is not an issue here.

The Court: I think that that is so.

Mr. Fleischman: The witness is awfully anxious to answer it and I think he should. I would like his answer.

Mr. Doran: Not an issue in this case.

The Court: Sustained.

Mr. Fleischman: Very good.

The Court: On the question of good faith, that is not an issue here."

Repeatedly, that same theory was emphasized by the Court to the Jury, to wit: that the question of good faith, integrity and fair dealing were not an issue to be decided by them.

The knowledge by the defendants, or either of them, as to the actual contents of the articles transmitted in Interstate Commerce, was also ruled immaterial.

The Buffalo Pharmacal Company, Inc., is a large pharmaceutical concern doing business in the City of Buffalo in the State of New York. It employs about thirty persons. The corporation does not itself manufacture or compound any drugs. It is just a dealer or a peddler of drugs, purchasing these drugs from the largest of the pharmaceutical houses in the United States and selling them to druggists throughout the United States in smaller quantities. It takes orders for drugs from physicians and when these orders are received by the corporation, its employees do nothing more than to pack these articles and ship them to these customers.

The respondent, Joseph H. Dotterweich, is now the president of the corporation defendant and its General

Manager. There is no proof in this case that he personally gave any instructions with reference to either of the shipments set forth in the informations, except that he admitted, as did the head of the shipping department, that general instructions had been given to the shipping clerk when the concern was organized, and that the shipping clerk used his own previous experience as well as his common sense in the conducting of that department of the corporation. Generally, the instructions then given by the respondent to his employees, that is to say, when the concern was organized in 1937, was that when orders came in and were filled by the manufacturing pharmacists and received from them, they were to be shipped to the person from whom the order was received. Nowhere in the record is it claimed that the respondent knew anything about these particular orders, the basis of these informations, or that he ever met the doctors who sent in the orders, or that he had ever himself solicited any business or even knew the towns where these physicians conducted their professions.

The convictions in the District Court rested upon the testimony of John S. Farries, who was a witness for the Government and an inspector for the Food & Drug Administration, which is one of the Federal Securities agencies. This witness claimed that his job is to travel around the country and pick up from physicians some of the drugs they bought and submit those drugs for test to the department at Washington to ascertain whether or not they contained the necessary strength or potency.

While on that mission, and on October 24th, 1939, he called upon a physician in Homer City, Pennsylvania, and purchased from that physician a small bottle containing Hinkle pills and forwarded that bottle to Washington.

Subsequently this same agent picked up a bottle containing digitalis from Dr. Taggart at Rock Creek, Ohio, in Feb-

ruary, 1940, and that he forwarded that bottle to the department at Washington. After an inspection and analysis by the authorities in Washington, the matter was reported by the Department to the District Attorney for prosecution, upon the ground that the bottle containing Hinkle pills stated on the label thereof that it contained some strychnine sulphate, which the Government contended, under the last edition of the National Formulary, which was not then printed, had been eliminated from the necessary make-up of Hinkle pills. The label on this bottle, it is admitted, contained the statement of all the ingredients of the particular pills, including, of course, the statement that it contained strychnine sulphate. However, the contention of the Government was that even though the label did correctly state just what it contained, it was nevertheless a violation, in that Hinkle pills, as contained in the formula, did not permit strychnine sulphate.

Hinkle pills have for many generations been used by families in America and throughout the world. It was originally a prescription of one Dr. Hinkle, who undoubtedly passed on long before any person now living was born, and while the Government still permitted the name of "Hinkle" for this simple drug, it did not allow the pill to contain the Hinkle formula. In other words, why a Hinkle pill is no longer a Hinkle pill and yet called by the Government a Hinkle pill, no one seems to be able to explain. If the Government did not like the Hinkle formula it could have forbidden its manufacture. To retain the name of Hinkle and have the public believe that it is the pill that they and their forebears have been using for generations, we respectfully contend is not a misbranding by any manufacturer of Hinkle pills but a misbranding by the Government. The Government admitted that one could send in Interstate Commerce pills containing the old Hinkle formula, which, of

course, contains strychnine sulphate, without violating the law, but as we get it, the Government claims that no one has the right to use the word "Hinkle" on the label, even though it does contain the Hinkle formula, and even though that label contains a correct description of its ingredients. In other words, the shipment into Interstate Commerce of tablets of Cascara Compond with strychnine sulphate is not forbidden, and although the ingredient strychnine sulphate is not removed, but the true name of the formula, viz, "Hinkle", is forbidden to be used. The information charges that such an act on the part of whoever was responsible for it, was "false and misleading" to a purchaser of Hinkle pills. However, not a single purchaser of Hinkle pills or any other person was called as a witness to testify that he was fooled or misled by the purchase of this bottle, or that he supposed that it did not contain strychnine sulphate, when as a matter of fact it did.

The informations with respect to the digitalis were also based upon the recommendation of the department in the first instance. In other words, the prosecution in this case did not originate with the District Attorney of the United States; it originated with the Department of Agriculture, or, as it is now called, the Food & Drug Administration.

When Mr. Farris, the Government agent, obtained the bottle of digitalis from Dr. Taggart, which had been purchased by Dr. Taggart from the Buffalo Pharmacal Company, and which it was stipulated by the defendants in the case traveled in Interstate Commerce to Dr. Taggart, and forwarded that article to the Department at Washington, it was there analyzed and it was found that the strength or potency was less than one half of the potency marked on the label. The digitalis as well as all other drugs sold by the defendant corporation in this prosecution was bought by it from Arner & Company, a very large and responsible manufacturing pharmaceutical concern.

The basis of the prosecution here was for both misbranding and adulteration.

It was admitted by the Government that no notice, pursuant to Section 335 of Article 21 of the Food & Drug Act, had been given by a representative of the department to the Respondent here, but that such a notice was given to the defendant corporation, the Buffalo Pharmacal Company.

The question which we sought to raise was, did the loss of potency occur and if so, how and where, or was it of a lower strength or potency when shipped. In other words, it was the contention of this respondent and of the corporation defendant that if this half-filled bottle of digitalis which had been frequently opened and which was taken from the shelf of Dr. Taggart, showed that its contents had but half the strength claimed for it upon the bottle, there was no proof submitted as to where this loss of strength took place. Digitalis is a type of drug which loses its potency or strength under many conditions. The Government has completely failed to eliminate the possibility of it having lost its strength or potency through the failure or neglect of parties other than the corporation defendant here. Since this is a criminal case, it was necessary for the Government to prove beyond a reasonable doubt that the loss of strength or potency of digitalis was caused through some act of commission or omission of the defendant corporation.

It was the claim of this respondent upon the trial and upon subsequent appeals to the Circuit Court that as an employee he could not be held liable under the circumstances under any conditions, except if he wilfully and knowingly did something that was wrong, that is to say, he either did something he should not have done or did not do something that he should have done; that the loss

of potency in digitalis was not due to any neglect on his part and that neither he nor the corporation knew or could have known of the condition that existed or could have learned of it in any way by any known tests; that the test as to potency as used by the Government was useless and unfair—that the so-called "frog" test was not a proper test and that the only fair test was the "cat" test, which contention has since been approved by the Government as the official test since the trial of this case; that the respondent was under no circumstances in this case liable even if the corporation could be in some way held liable; that the loss of potency occurred subsequent to the shipment in Interstate Commerce by conditions over which neither the respondent nor the corporation had any control; and; lastly, that the failure to convict the corporation defendant, the owner of the business, did not allow the conviction of the respondent individually for a crime which is not *malum in se* but *malum prohibitum*.

This case is very important to this respondent in that he is a man who the Government admits acted in good faith and complete fairness and integrity and who has been convicted of three misdemeanors—crimes against his own Government. This not only affects his personal standing in the community, of which he has been heretofore an honored member, but his standing in the business world as well. He is now looked upon as one who adulterates and misbrands his drug products, and, therefore, a man without honor in his business dealings, a situation which will destroy this large business established by honesty and perseverance.

POINT ONE.

It is necessary under the Act, and an indispensable requisite, that notice as required by Section 335 should be given by the Government to this respondent before the beginning of any prosecution.

It is conceded by the Government that the respondent was not served with notice of any hearing which affected him, as required by Section 335 of the Act, before the matter was reported by the Secretary to the United States Attorney. This important question, raised many times upon the trial, was whether such a notice is necessary before the institution of a criminal prosecution by the United States Attorney. The answer has not been given by the Courts since the new Act of 1938.

It is quite important that we have before us the old Act, that is to say, the Act prior to 1938, as well as the present Act, and to simplify the argument we have set forth the old Act and the present one side by side.

OLD ACT—Section 11—Title 21:

"The examinations of specimens of food and drugs shall be made in the Bureau of Chemistry in the Department of Agriculture * * * and if it shall appear from any such examination that any of such specimens is adulterated or misbranded, the Secretary of Agriculture shall cause notice thereof to be given to the parties from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard * * * and if it appears that any of the provisions of said sections have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States District Attorney."

NEW ACT—Section 335—Title 21:

"Before any violation of this chapter is reported by the Secretary to any United States Attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views either orally or in writing, with regard to such contemplated proceeding."

Prior to the adoption of the new Act of 1938, the cases construing Section 11 of Title 21, which is the section which required notice to be given, were at variance, but in 1911 this Court, in the case of United States vs. Morgan, reported in 222, U. S. 274, determined that the notice and hearing provided for in that Act was not a condition precedent to the commencement of a prosecution. This Court, in that case, speaking through Mr. Justice Lamar, emphasized that if it had been the intention of Congress to make the giving of a notice a condition precedent, "the Statute would have required that a hearing should be given to all persons charged with the violation of the Act and not merely to those from whom the sample was received." That decision, therefore, settled the law upon that question. Under the old Act there was a requirement that where the proceeding was instituted in the first instance by the Secretary of Agriculture, who then had this character of prosecution in charge, that then the Secretary of Agriculture should give notice thereof to the parties from whom the sample was obtained. Under the old Act, upon the facts as we have them in this case, the notice would have to be served by the present bureau upon Dr. Taggart, who is the physician in the rural community to whom these pills were sold.

There was no change by Congress of the Food & Drug Act after the decision of United States vs. Morgan, *supra*, until the adoption of the present law by Congress in 1938. In this new law Congress used the precise language of Section 11 that Mr. Justice Lamar in the Morgan case said it should use if it wanted to make notice a condition precedent. What stronger proof can there be of legislative intent?

In the new Act notice was no longer required to be given to the person from whom the sample was received, but to the person against whom the proceedings were contem-

plated. One of the reasons for the requirement of the notice is explained by Section 336 of the present law, which in substance states that if the Secretary is satisfied that the offense was a minor one, no further action need be taken. This is understandable because where the law, as here, is arbitrary, and creates a crime which is *malum prohibitum* and only that, the Court should not be asked to stamp a man a criminal where the same salutary effect could be obtained by a mere warning.

Then again there was before Congress undoubtedly the same question as the one before the Court in the Morgan case—should the minor employee, the shipping clerk in a very large concern, the wrapping clerk, the boy who takes the packages to the post-office—in other words, the person who actually introduces into Interstate Commerce the misbranded product be held criminally responsible, even though the contents of the package are unknown and unascertainable to him? If, therefore, the respondent or any other employee of a corporation, against whom such proceedings were contemplated, were to receive notice, it would give him an opportunity to appear before the Secretary or his representative and point out that in no way did he have anything to do with the transaction in a criminal capacity.

In 1939, almost immediately after the passage of this new law, in "Law and Contemporary Problems," which is a publication of the School of Law of Duke University, there was an article entitled "The Enforcement Provisions of the Food, Drug & Cosmetic Act," written by Frederic P Lee, who was the Government's counsel to the United States House of Representatives and the United States Senate and special counsel to the Secretary of Agriculture and a professor of Statute Law at Georgetown University

Law School. In volume 6 on page 74 he calls attention to the very matter with which we are concerned. He says:

"The new Act specifically provides that before any violation is reported by the Secretary of Agriculture to any United States Attorney for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and opportunity to present his views, either orally or in writing, with regard to the contemplated proceeding. * * * The old Act also provided for such a hearing, although the language was ambiguous and was construed by some courts as requiring administrative hearings preliminary to libel for condemnation as well as criminal proceedings. Further, the new Act adopts the administrative construction previously placed on the old Act."

"Under the old Act the United States Attorney had the duty of instituting criminal proceedings upon report of any violation by the Secretary of Agriculture. He was bound to accept the findings of the Secretary and not make any other independent investigation to satisfy himself. However, the United States Attorney could also under other general provisions of the law, on his own initiative, institute proceedings irrespective of receipt of any report by the Secretary of a violation. In such event the Statute required no preliminary administrative hearing. The new Act omits the mandatory duty of the United States Attorney to prosecute at the Secretary's directions. In consequence the District Attorney has discretion in all instances as to whether criminal proceedings will be instituted. The right to a preliminary administrative hearing still exists only when the Secretary reports the violation. * * * Nevertheless the administrative hearing constitutes a real protection against unfounded criminal prosecutions in food and drug cases, for it is only rarely that the United States Attorney institutes such prosecutions otherwise than at the instance of the Secretary."

In 1942 a book entitled "A Treatise on the Law of Food, Drug & Cosmetics" was published. It was written by Harry Aubrey Toulmin, Jr., J. D., Litt. D., L. L. D. So far

as we know this is the first publication on the law of Food, Drugs and Cosmetics since the new law. On page 609 of that publication is an article entitled "Monograph Prepared by Food & Drug Administration Officials for Guidance in Administrative Procedure," prepared under the direction of Masten G. White, Solicitor, Ashley Sellers, Head attorney Office of Solicitor, and Nathan D. Grundstein, Research Assistant Office of the Solicitor.

On page 737 of the book entitled "The Law of Foods, Drugs & Cosmetics," which is page 277 of the Monograph, the question we are concerned with here is discussed as follows:

> "The present Food, Drug & Cosmetic Act has not sought to change the administrative character of the hearing. The text of Section 305 does not contain any reference to the word 'hearing,' stating only that when the person against whom a criminal proceeding is contemplated 'shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.' Such a procedure is required only 'before any violation of this Act is reported by the Secretary to any United States Attorney for institution of a criminal proceeding," *with the inescapable inference, therefore, that Section 305 was intended to overrule to this extent the effects of United States vs. Morgan on the jurisdictional aspects of the pre-prosecution proceeding.*" (Italics ours.)

The author of that book, on page 81 of that volume, himself agrees with this contention and refers the reader for a further discussion of the subject to the Monograph aforesaid.

We want to emphasize that it would have been of considerable benefit to this respondent to have received this notice of contemplated action, because under Section 333, sub-division C, Title 21, he could have proved to the Secretary that he was protected. That section reads:

"No person shall be subject to the penalties of subsection A of this section for having received in Interstate Commerce any article or delivered it, or proferred delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him."

It appears clear, in the present case, from the testimony of the representative of the Secretary, that no notice was given to the respondent (R-115-116) and that no request was made for any information and that the agent knew that he could have obtained this information had he asked for it (R. 118). It is to be noted particularly that the question of notice pursuant to Section 335 of Title 21 was intended to be given to the parties who it was contemplated would be made defendants in a criminal action because notice was given by the Department to the corporation defendant.

POINT TWO:

The respondent was the agent of the defendant corporation and some wrongful act on his part must be shown.

It was claimed by the Government that the respondent was general manager of the corporation and for that reason and because the corporation of necessity can only act through its officers or manager, the respondent could be held responsible.

This claim, in our opinion, brought about the conviction in the District Court of this respondent. This proposition was put squarely to the jury by the Court in its statement that the humblest employee, regardless of intent, could be prosecuted and convicted under the law. In view of such a statement the jury could well feel bound to convict a more important officer.

We refer to pages 62 and 63 of record:

"Mr. Fleischman: I started out to say that we will prove that we used the very best stuff—

The Court: I see no need for this argument. It makes no difference. If you have some other argument I will be glad to listen to it. In view of the Statute, no matter what the intentions were, no matter how good their reputation was, it is immaterial. The Statute makes it as it is.

Mr. Fleischman: As we stand here we have an individual, the defendant here, and I think we have the right to prove the good faith as we stand now.

The Court: I cannot follow your argument and I cannot see the difference between the individual and the corporate business.

Mr. Fleischman: We will assume that our office boy sent out some stuff from a responsible concern. He takes it off the shelf and sells it. He has every reason and right to suppose that it came from a very reliable concern, perhaps the most responsible in the country, and he sends it out, and your contention, as I get it now—

The Court: I think I would be glad to rule that the office boy would be equally guilty.

Mr. Fleischman: That is the proposition on which you are now ruling?

The Court: Yes."

The evidence in this case shows no directions or instructions by the appellant to anyone as to this particular shipment or as to any other particular shipment (Record 129.) The corporate defendant deals in a great many pharmaceutical products and the items named in the information in this case are extremely small as compared with its volume of business. As in any other large concern, the general manager issued general instructions regarding orders, inventory, shipments, etc., to his fellow employees. It is nowhere claimed, in fact it is repeatedly denied by the Government, that Mr. Dotterweich gave any instructions to carry on any unlawful activity. The crime, if there was

a crime, was clearly *malum prohibitum* and was committed by the corporation, not its employees. We have repeatedly contended that the law does not impose the same liability on the agents as it does on principals in cases *malum prohibitum*. The best proof of this lies in the fact that the law provides a protection to the principal by granting him immunity from prosecution if he produces a guarantee. No such guarantee can run to an employee. Can it be argued that the Legislature intends to be harsher with the agent than the principal? It is admitted by the learned Attorney General that it was not necessary for the respondent to secure a guarantee from the seller of the product to the corporation, and it is also admitted that there was not such a relationship between the respondent here and the seller of the merchandise as would permit the respondent to ask for a guarantee for himself. This guarantee applies only to the purchasers, and this respondent had no dealings with the seller.

It is interesting to note that prior to the Drug Act of 1938, there was a section (Section 4) in this very law which provided that the act of the corporation was also the act of the individauls composing that corporation, and that this very section was, under the laws of 1938, when the new drug law went into effect, completely deleted. Why? It seems to us that it was deleted, first, because if the crime was *malum in se*, it was unnecessary to have that clause, because under the common law, the officers of a corporation or its employees who participated in the doing of something which was wrong, were clearly guilty with the corporation, and if the offense was malum prohibitum, Congress did not want the employees punished for the doing of things against which they had no protection.

The learned Attorney General argues in his brief, page 33: "We believe however, that the Statute should be con-

strued to relieve clerks of liability in proper cases, since it is inconceivable that Congress intended to spare clerks who acted with intent to defraud or mislead or who negligently and contrary to instructions acted so as to cause a violation of the Act."

We have no fault to find with that thought on the part of the Attorney General. We agree with him that it is the law and should be the law if it is not, that every employee of a corporation should be held responsible for a crime of the corporation where that employee knows that the actions of the corporation are criminal. In other words, it is a crime *malum in se* and the clerk participates, aides and abets in the commission of that crime. However, we believe it to be most absurd to say that Congress intended to hold an employee responsible for an offense which that employee, no matter how careful, no matter how honest, no matter how decent and law-abiding he may be, could not by the most deligent effort know about.

The learned Attorney General says in his brief that it must be left to the good judgment of the administrative officer to determine who is to be prosecuted. We are in complete disagreement with that contention. Are we to depend for our liberty and our honor upon the caprice or, shall we say, the kindness or the particular liking for us by any district attorney? Even assuming that he is the present occupant of that respected office, who in our opinion is a fine gentleman of unquestioned honor and integrity. Tomorrow there may be a different kind of a prosecutor and where it is discretionary with the District Attorney as to who to prosecute, it may be that that particular district attorney has a dislike for the vice president of a corporation and a strong liking for the president of the corporation, and since he can designate who shall be held responsible for an offense *malum prohibitum*, he may prosecute whichever of the officers he does not like.

The charge here is not conspiracy. It cannot be conspiracy, because conspiracy requires intent. Yet this respondent is charged as a principal because he was an employee of the corporation.

The appellant's brief is in error in its footnote on page 26. If the respondent had ordered this digitalis, knowing that it was not up to proof, he would be guilty even if he was the office-boy. That contention is not disputed by the respondent. Once we have knowledge that a thing is wrong, then we leave the field of an offense *malum prohibitum* and enter the field of *malum in se*. We know we are doing something which is wrong and wicked and there it makes no difference what position we occupy with the corporation, important or otherwise, we are a part of the guilty scheme—we are conspirators in the doing of a guilty act. All of that is not present in a case of where we had no intent to do wrong, could not know that it was wrong, and even by the most diligent efforts could not ascertain that it was violative of any section of the law. Surely it is clear to the Government that this respondent did not know that this drug was misbranded. Even if it was, it was not possible for this respondent to take each item as it came from a responsible pharmaceutical concern and himself make some test, even if there was such a test. It stands to reason that it is impossible to make a test upon each pill of the thousand that go into a bottle which sells for $1.60, and yet it is the Government's contention that if any one of those pills, for whatever reason, fell below its marked potency or strength, that a crime is committed.

In the recent case of the Direct Sales Company vs. United States, 63 U. S. Supreme Court, 1265, which has no connection with this respondent or with the corporation with which the respondent is connected, except that they are both located in the City of Buffalo, New York, the convic-

tion was sustained upon the theory that the corporation knew or should have known that the large quantity of morphine it was selling to a physician in a very small community, must have given it notice that its product was being used for illegal purposes. This is understandable; this is not *malum prohibitum*. This character of sale in these very large quantities of a very dangerous drug to a physician in a small community should have put the corporation on its guard as to the uses to which the commodity was to be put, and Mr. Justice Rutledge, speaking for this Court, in our opinion correctly stated that the corporation there had notice of what was being done with its drugs was illegal, and yet in that case no individual member of that corporation was held liable.

In the case of Boudreau, Special Assistant Attorney General, against McDowell, reported in 256 U. S. 465, Mr. Justice Brandies, dissenting with Mr. Justice Holmes, had occasion to use this pregnant thought, which we respectfully submit applies in this case:

> "Respect for the law will not be advanced by resorting in its enforcement to means which shock a common man's sense of decency and fair play."

As we view it, holding an employee responsible in the sale of a misbranded product over which he had no control, and the contents of which were completely unknown to him, without more, would certainly shock a common man's sense of decency and fair play.

The Government's contention is that while it is true that now and then an innocent man might be convicted, one who had no knowledge and could not have any knowledge of any wrongdoing, yet the law reads that intent is not necessary and that person must be convicted.

That theory brings us back to the Biblical days when one was punished for a crime consisting of a wrongful thought,

and where one possessed such a wrongful thought it was necessary for him to sacrifice a goat or a sheep or a ram, but an animal without a blemish (otherwise it was not acceptable) and offer him as a sacrifice upon the altar of his God for having sinned without intent, evidently the Attorney General thinks that some such law must be resurrected, that a goat was necessary to be sacrificed, and so they selected this case, and we must agree that they thought they did select an animal without a blemish, an upright, decent and honest citizen, the respondent here, as the sacrifice. But until and unless that theory of crime and punishment is again recognized in civilized communities, it cannot be the law that an innocent employee of a large corporation can be held liable for a crime which is *malum prohibitum* and in the doing of which the respondent had no knowledge or intent or purpose to in any wise do any act contrary to the laws of this country, and yet the unblemished record which his forebears have handed down to him through the generations no longer can be handed down to the future generations, because without knowledge and without intent and with no purpose to do wrong, a bottle of drugs is sent in Interstate Commerce by someone other than the defendant, which in the course of that travel, for some reason unknown to anybody, loses its potency, and which makes the respondent an employee of the corporation guilty of misdemeanors against the Government of his own country.

POINT THREE.

The facts are as consistent with innocence as with guilt.

The respondent has consistently urged that the Government has failed to prove beyond a reasonable doubt that the digitalis found in the possession of Dr. Taggart was of a

lesser potency than labeled when it was shipped by the corporate defendant.

The defendant corporation purchased these drugs from a very large and responsible pharmaceutical concern, Arner & Company. There was no connection between Arner & Company and the defendant corporation in any way except that as seller and buyer. Arner & Company sold to the defendant corporation the shipment in question, to wit: a total of 1,500,000 tablets of digitalis. This is a comparatively small order. Arner & Company was the sole seller of this product to the defendant corporation. If the Government discovered a single bottle of Arner & Company product of digitalis, containing less potency or strength than was marked upon that bottle, they had the right to investigate the books of the defendant corporation and find out to whom the drug had been shipped. The duty of the Government would be in that case, in view of the character of the drug, to go to every doctor to whom such drug was sold and examine the supply of digitalis. They would further advise the defendant corporation, an innocent purchaser of this drug, of the condition of the drug and have it call the drug back from those to whom it was sold. Is it possible that the Government of the United States, upon discovery of this drug marked one and one-half grains, and actually containing only one-half of that strength, would rest upon what they found in a single opened and half used bottle? We charged upon the trial that if the respresentative of the Government did that they would be guilty of criminal negligence, and we mean just that. On the other hand, we had no way of proving that, as a matter of fact, the Government's agents did not go to a great many other doctors to whom we sold this drug and found the same product sold at about the same time and when tested found that it cont[illegible]ed exactly what it was sup-

posed to contain. If that were the case it would then be clear that the bottle of digitalis, which was found in the possession of Dr. Taggart, had by reason of some external condition reduced its potency, and that, therefore, when it left the factory of Arner & Company and was shipped to the defendant corporation and by it introduced into Interstate Commerce, had its full potency.

Many different elements may cause the reduction in the potency of digitalis—heat, light, lack of refrigeration, moisture and some other matters that the experts are unable to determine. The experts agreed that there is some such thing that causes a loss of potency. The bottle of Dr. Taggart had been opened. If the doctor prescribed tablets over a period of time, approximately 250 times, it certainly was not kept refrigerated and nobody paid any particular attention to its being kept in a cool place where neither heat nor light would affect it, and evidently in some way some of these things that do affect the potency of digitalis did affect this bottle, so that when the inspector came and purchased the bottle from the doctor, it did not have the full strength or potency as labeled.

The testimony through the trial on the question of what causes deterioration is most illuminating, or maybe we shall say is most lacking in illumination. The first Government expert Mr. Braun, to whom these products were sent, finally ended up his examination (Page 56 Record):

> "Q. Let me make it simple. Do you, as a matter of fact, tell us from your experience as an expert that moisture does have an affect on the potency of digitalis?
>
> A. To tell you the truth, I never worked on deterioration of digitalis. I am not a fit witness on that so far as that is concerned."

This witness was followed by one Lloyd C. Miller, who does the analyzing for the Government when Mr. Braun is

not present, and his contention was that the only thing that will cause digitalis to lose its potency is "cooking." (R. 88.) This witness calls the U. S. Pharmacopeia, the Bible of the profession and "we have to follow it." (R. 92.) "It is prescribed by the Act under which we work, and we cannot pick up any other method that we might think was almost as good or might be easier. We have to follow that one." (R. 72). That sounded very well to the jury. It was his contention that there was no other test for the potency of digitalis than the "frog" test. He had never heard of the "cat" test. As a matter of fact, he wanted to know from us whether we were talking about the "cat's eye" test, (R. 90-91), and finally ended up by saying that he did not know what causes the loss of potency in digitalis other than "cooking." It was his claim that moisture did not do it. It was his claim that refrigeration did not do it and the only thing that would do so would be "cooking." It was very evident that Dr. Taggart did not do any "cooking." Everything seemed to have gone well with this expert and his faith in the Bible of the chemical profession was sublime until his attention was called to the fact that the Bible of the fraternity, on page 137 of the United States Pharmacopeia, it says: "Storage to preserve powdered digitalis in waterproof and air-tight containers and protect it from light."

He was then asked why that was put into the United States Pharmacopeia and his reply was:

> "A. Just a precautionary measure. I don't know why they are required, but I heard a lot of manufacturers complaining about it" (R. 92.)

Just previous to that he stated that he didn't care what the manufacturers complained about it and that if the National Formulary and the Pharmacopeia says that is so, that's all there is to it. The attention of this expert was then called to the fact that he himself, when sending

the specimens from Washington to Dr. Chapman at Baltimore, sent them refrigerated, and his reply was that he did not recall having given such testimony.

The only real expert called by either side was Dr. Chapman. He is a teacher of pharmacology at the University of Maryland. The specimen sent to him, which was obtained from Dr. Taggart, was below the potency, but he stated that merely meant that this particular bottle had lost its potency. Dr. Chapman stated that he believed in the "frog" method of analyzing digitalis, and even so good an expert as he was wrong, because he had hardly finished testifying before the Government changed the method of assaying digitalis from the "frog" method to the "cat" method. During this entire trial every expert for the Government belittled and laughed at the "cat" method as a test of digitalis.

In short, the failure of the Government agents to produce other samples which they must have traced, the confusion among the experts as to the proper tests for the potency of digitalis, and the apparent likelihood of external forces causing a reduction in potency present serious doubts as to where the detrioration occurred. It surely is not established beyond a reasonable doubt that the digitalis was under strength when it was shipped by the corporate defendant.

It is, therefore, respectfully submitted, that the judgment of the Circuit Court of Appeals be affirmed and that the informations filed against this respondent Joseph H. Dotterweich be dismissed.

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